

GSK Public Policy positions

Engagement with Patient Organisations

The Issue

Patients are crucial stakeholders for GSK. Our engagement with patient organisations helps us to better understand the needs of patients and their illnesses, which in turn helps to guide our R&D, as well as our policies. At the same time, we hope that our support can help them better champion and represent the voice of the patient in the healthcare policy environment.

We believe unequivocally in the independence of patient organisations and we go to great lengths to ensure our relationships with them are open and transparent. We understand that there is significant scrutiny of the relationship between pharmaceutical companies and patient organisations. We welcome this attention, and have established rigorous standards to govern our interactions with patient organisations that are aligned with GSK's values of respect, transparency and integrity, and help to ensure and safeguard the independence of the groups with whom we engage.

This paper sets out GSK's approach to working with patient organisations, the rationale for engaging with them and the standards we apply to our interactions to ensure we conduct ourselves appropriately, ethically and transparently.

GSK's Position

- GSK's values of integrity, respect, patient focus and transparency underpin all our engagements with patient organisations.
- We have a dedicated above-country team, along with equivalent functions at an individual country level, who work to ensure that GSK's R&D and business strategies are informed by an understanding of patients' needs and concerns.
- These teams e.g., Medical, Communications, Government Affairs, operate separately from the commercial function, reflecting the robust governance we have in place to ensure engagement with patient organisations is independent from commercial influence. GSK's work with patient organisations is regularly reviewed at Board level by the Corporate Responsibility Committee.
- GSK recognises patient organisations as key stakeholders within the healthcare debate, and we believe it is essential that the patient perspective is well represented before policy makers. As such, we work with patient organisations from all therapeutic areas, not just those aligned with GSK's core disease expertise, to understand their needs and to help patient organisations build their advocacy capabilities.
- We believe in the independence of patient organisations and we are committed to ensuring that our collaborations with these groups are both proportionate and appropriate. We do not promote our medicines to patient organisations, we do not ask patient organisations to promote our medicines on our behalf, nor would we ever ask them to endorse our medicines in any way. All discussions around disease management or medications is approved and undertaken by GSK Medical and R&D colleagues.
- GSK adopts an arm's length approach to funding patient organisations designed to remove any real or perceived conflict of interest. In addition to project support, the provision of unrestricted grants in response to unsolicited written requests to support the day to day running of a patient organisation is a key element of this approach.
- We maintain strict funding procedures that exceed what may be legally required and will not provide any more than 25% of the total funding received by a patient organisation during any calendar year. By limiting our support in this manner, we aim to minimise the risk of an organisation becoming reliant on GSK for support, and thereby reduce the potential for conflicts of interest.

- We place a premium on transparency. GSK was the first company to disclose all of our payments to patient organisations on our external website (<http://www.gsk.com/en-gb/responsibility/responsibility-reports-and-data/patient-group-funding/>), a practice which has now become standard across the pharmaceutical industry.
- We have a number of platforms in place to ensure patients' interests are respected and we have embedded this into the way we work at the very highest levels of the company. These include a Health Advisory Board focused on Europe, set up in 2004, and another made up of representatives from respiratory patient organisations. Through these forums, we consult and share our thinking with leading patient organisations on key GSK policies and external developments. They have over the years given us guidance on our disclosure of payments made to HCPs and on an emerging strategy to bring patient insight systematically and comprehensively into GSK R&D.
- We are committed to ensuring the patient voice is embedded into our R&D processes. Through patient interviews during the drug design phase, we hope to adapt our clinical trial models to include more real world data and therein ensure that patient interests are more centrally represented throughout our drug development cycle.

Background

Definition of a Patient Organisation

There is no globally recognised definition of a patient organisation. The term can encompass a wide array of patient advocacy groups and patient support groups. Some provide education and information to their members, while others also advocate and influence healthcare policy. As an integral part of improving standards of care, patient organisations are important stakeholders for GSK, and we value the role they play in the healthcare environment.

To help ensure the appropriateness of our interactions with patient organisations, we ask that in order to receive funding or partake in any joint work, the organisation must:

- Be a credible, legitimate patient organisation with official or legal status.
- Have or aim to have a majority of patients and/or carers on the board (except in the US where local law prohibits such a condition).
- Have robust governance processes such as a constitution, bylaws, or an audit function.
- Be transparent about funding, with an annual report or equivalent official documentation.
- Be non-profit making.

Management and Oversight

Our Global Patient Advocacy Team is dedicated to overseeing and co-ordinating engagement with patient organisations at a global level and is supported on the ground by Patient Advocacy Coordinators in the countries in which GSK operates. To help standardise the work of these Coordinators and to drive our patient centred approach throughout the business, we have in place a *Global Standard for Interacting with Patient Organisations* which covers the following areas:

- The type of funding available to patient organisations.
- Documentation and disclosure procedures relating to the funding of patient organisations.
- The various internal roles used to co-ordinate and oversee GSK's engagement with patient organisations including Patient Advocacy Coordinators and Relationship Managers.
- Principles around how we engage with patient organisations aimed at advancing the development of medicines. This engagement is approved and conducted by Medical and/or R&D colleagues.

The above roles exist within teams e.g., Medical, Communications, Government Affairs, which operate separately from the commercial function, reflecting the robust governance we have in place to ensure engagement with patient organisations is independent from commercial influence. GSK's engagement with patient organisations is regularly reviewed at Board level by the Corporate Responsibility Committee.

Funding Types and Principles

GSK supports patient organisations across the world in a number of ways.

- Core funding (ie. an unrestricted grant to support the day-to-day running of a group).
- One-off project funding to help patient organisations conduct a specific event or activity.
- Skills training in leadership, negotiation, communications, fundraising and planning etc.
- Collaboration around disease awareness/prevention projects.
- In-kind support, such as agency support for media outreach.

We believe that all patient organisations should function independently and be free from undue influence. Our funding adheres to the following principles:

- We will not provide more than 25% of the total funding received by a patient organisation during any given calendar year. The only exception to this is for rare disease patient organisations or start-up patient organisations, which can receive up to 50% of the total funding, by exceptional approval by the Senior Medical Officer of the business unit, region or country.
- We do not ask to be, and will not be, the sole funder for major projects with patient organisations.
- We do not seek product support from patient organisations; we will not fund disease awareness campaigns connected to a GSK product in development.
- We do not directly fund individuals, in their capacity as representatives of patient organisations, to attend medical and other healthcare professional meetings (unless they are attending as a speaker or there is a specific patient work stream).

Each country, business unit or region has a Grants and Donations Committee in place for approving patient organisation funding, as well as a defined process for reviewing funding requests.

Disclosure of funding

We disclose all support given to patient organisations on our external website, including financial support and/or significant indirect/non-financial support (<http://www.gsk.com/en-gb/responsibility/responsibility-reports-and-data/patient-group-funding/>). We were the first company to disclose this information and in doing so have helped to provide a benchmark for the rest of the industry since 2007.

Bringing the Voice of the Patient into GSK

To guide our research, it is essential for us to understand the needs of patients and the impact that our medicines can have on their lives. GSK has a number of patient-focused initiatives in place aimed at bringing the voice of the patient into our R&D programmes.

"Focus on the Patient" Programme

In 2005 we launched an internal programme to bring patients and representatives of patient organisations to GSK sites to speak directly to our scientists, researchers, physicians and other employees about their healthcare needs. Since its inception, the programme has delivered over 80 global seminars on a wide variety of diseases, bringing to life what it is like to live with an illness. The programme has evolved to facilitate patient involvement in research activities and discussions which has helped strengthen the patient voice in GSK.

European and Respiratory Health Advisory Boards (HABs)

The primary purpose of the HABs is to bring the insights of patient organisations into GSK and to look at key policies and issues from the perspective of the patients they represent. The HAB discussions are conducted under Chatham House Rules, to encourage open, sincere and productive discussions. Insights gained from the HABs are instrumental in helping GSK create a more patient focused R&D model.

Patient Advocacy Leaders Summits (PALS)

Every year, we bring diverse groups of patient organisations together through our Patient Advocacy Leaders Summits (PALS) to build understanding, develop skills and identify ways to collaborate appropriately. In 2017 we conducted PALS in the Czech Republic, Germany, Japan and Switzerland.

Capability building and In-Kind Support

We believe that the voice of the patient should be central to the development of healthcare policy and are committed to helping patient organisations inject their perspectives into healthcare debates around the world. To help them build their capabilities, GSK provides training in media outreach, communications and general management skills, increasing the capacity of patients to be effective advocates with meaningful involvement in areas like drug discovery and non-clinical testing, planning and conduct of clinical trials and regulatory affairs.

At an above-country level, we are founding members of the European Patients' Academy on Therapeutic Innovation (EUPATI), a consortium project funded by the European Union's Innovative Medicines Initiative, aiming to increase the capabilities of well-informed patients and patient organisations to be effective advocates with regulatory authorities, HTA bodies, industry and within ethics committees about medicines research and clinical trials.

As a member of EUPATI we contribute expertise, staff time and funding to develop in-depth training courses and support qualitative research to help patients in 12 European countries become more effective advocates during the R&D of new medicines.

October 2018